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## NOTICE OF ALLOWANCE AND FEE(S) DUE

2352 7590 12/18/2008

OSTROLENK FABER GERB & SOFFEN  
1180 AVENUE OF THE AMERICAS  
NEW YORK, NY 100368403

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/18/2008

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/774,358      | 02/05/2004  | William Stern        | P/546-279 R/ISSUE   | 8408             |

TITLE OF INVENTION: NASAL CALCITONIN FORMULATION

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO           | \$1510        | \$0                 | \$0                  | \$1510           | 03/18/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

**PART B - FEE(S) TRANSMITTAL**

Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
**or Fax** (571) 273-2885

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

2352 7590 12/18/2008  
**OSTROLENK FABER GERB & SOFFEN**  
1180 AVENUE OF THE AMERICAS  
NEW YORK, NY 100368403

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

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| EXAMINER           | ART UNIT | CLASS-SUBCLASS |
|--------------------|----------|----------------|
| HAGHIGHATIAN, MINA | 1616     | 424-043000     |

|  |  |
|--|--|
| 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).   | 2. For printing on the patent front page, list   |
| <input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  | (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  |
| <input type="checkbox"/> "Fee Address" indication (or "Fee Address" indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. | (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. |

## 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

|   |  |
|---|--|
| 4a. The following fee(s) are submitted:                                       | 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)  |
| <input type="checkbox"/> Issue Fee  | <input type="checkbox"/> A check is enclosed.  |
| <input type="checkbox"/> Publication Fee (No small entity discount permitted) | <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.  |
| <input type="checkbox"/> Advance Order - # of Copies _____                    | <input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form). |

|  |  |   |
|--|--|---|
| 5. Change in Entity Status (from status indicated above) | <input type="checkbox"/> a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. | <input type="checkbox"/> b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). |
|--|--|---|

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS; SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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| 2352   | 7590        | 12/18/2008           | EXAMINER            | HAGHIGHATIAN, MINA      |
| OSTROLENK FABER GERB & SOFFEN<br>1180 AVENUE OF THE AMERICAS<br>NEW YORK, NY 100368403 |             |                      | ART UNIT            | PAPER NUMBER            |
|  |             |                      | 1616                | DATE MAILED: 12/18/2008 |

## Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

|                               |  |  |
|-------------------------------|--|--|
| <b>Notice of Allowability</b> | <b>Application No.</b><br>10/774,358<br><b>Examiner</b><br>MINA HAGHIGHATIAN | <b>Applicant(s)</b><br>STERN, WILLIAM<br><b>Art Unit</b><br>1616 |
|-------------------------------|--|--|

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Amendments, remarks, IDS & Declarations of 11/10/08, 11/17/08, 11/21/08 and 11/24/08.

2.  The allowed claim(s) is/are 13,14,16,17,19,24,27,31,32,34 and 45.

3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All    b)  Some\*    c)  None    of the:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.

(a)  including changes required by the Notice of Draftperson's Patent Drawing Review ( PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_.

(b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- 1.  Notice of References Cited (PTO-892)
- 2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date See Continuation Sheet
- 4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
- 5.  Notice of Informal Patent Application
- 6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_.
- 7.  Examiner's Amendment/Comment
- 8.  Examiner's Statement of Reasons for Allowance
- 9.  Other \_\_\_\_.

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 07/30; 08/21; 09/08; 11/10 and 11/24/08 .

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The closest prior art, does not teach or suggest a formulation comprising calcitonin and citric acid or a salt thereof for intranasal administration in a concentration-dependent manner with enhanced bioavailability and shelf stability, wherein the concentration of citric acid or a salt thereof is the critical element. Applicants have discovered that the narrow concentration range of 10-25 mM of citric acid and/or a salt thereof gives the formulation both of its enhanced bioavailability and shelf stability. The term "citric acid **and/or** salt thereof" used in the specification is interpreted by the Office to support the term "combined concentration" used in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghigatian/

Mina Haghigatian  
Primary Examiner  
Art Unit 1616